

# Terrestrial Animal Health Standards Commission Report

September 2007

## USA Comments

### APPENDIX 3.8.X.

## GUIDELINES ON SURVEILLANCE FOR NEWCASTLE DISEASE

### Article 3.8.X.1.

#### Introduction

This Appendix defines the principles and provides a guide on the surveillance for Newcastle Disease (ND) ~~complementary to in accordance with~~ Appendix 3.8.1., applicable to countries seeking to demonstrate recognition for a declared ND status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of ND status is also provided. ~~This Appendix complements Chapter 2.7.13.~~

Surveillance for ND is complicated by the known prevalence of avian paramyxovirus serotype 1 (APMV-1) *infections* in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic poultry. Consequently it is required that APMV-1 isolates synonymous with Newcastle disease ~~virus~~ virus (NDV) be characterized to differentiate those *infections* of virulent NDV (vNDV) that are notifiable ~~as defined in Chapter 2.7.13.~~ from those of low virulence (loNDV) which are not. Newcastle Disease (ND) is ~~described~~ defined in Chapter ~~xxx 2.7.13 as an infection of birds with APMV 1, however this appendix is only concerned with vNDV infections of poultry).~~

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific guidelines for all situations. Therefore surveillance strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from vNDV *infection*.

Surveillance for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from vNDV *infection*.

### Article 3.8.X.2.

#### General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary ~~Administration~~ Authority*. In particular there should be in place:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or vNDV *infection*;
  - b) a procedure for the rapid collection and transport of samples from suspect cases of ND to an ~~approved~~ *laboratory* for ND diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic and surveillance data.
2. The ND surveillance programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary ~~Administration~~ Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to an ~~approved~~ *laboratory*. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in ND diagnosis and control;
  - b) implement, when relevant, regular and frequent clinical, virological and serological surveillance of high risk groups of poultry within the target population, (e.g. those adjacent to an ND infected ~~population~~ *country, zone, compartment*, places where birds and poultry of different origins are mixed, or other sources of vNDV).

An effective surveillance system may periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to vNDV *infection*. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from vNDV *infection* should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

#### Article 3.8.X.3.

### Surveillance strategies

#### 1. Introduction

The principles involved in surveillance for *disease / infection* are technically well defined. Any surveillance programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of surveillance programmes to prove the absence of vNDV *infection*/circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a country wishes to declare freedom from vNDV *infection* in a country, *zone* or *compartment*, the sub-population used for surveillance of the *disease / infection* should be representative of all poultry within the country, *zone* or *compartment*. Multiple surveillance methods should be used concurrently to accurately define the true ND status of poultry populations. Active and passive surveillance for ND should be ongoing with the frequency of active surveillance being at least every 6 months. Surveillance should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual* (Chapter x.x.x.x). If alternative tests are used they must have been validated as fit-for-purpose in accordance with OIE standards. A country should justify the surveillance strategy chosen as adequate to detect the presence of vNDV *infection* in accordance with Appendix 3.8.1. and the prevailing epidemiological situation.

For random ~~surveillance surveys~~, the design of the sampling strategy will need to ~~incorporate be~~ ~~of an~~ epidemiologically appropriate design ~~to demonstrate the prevalence of vNDV infection~~. The sample size selected for testing should ~~to~~ be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The ~~applicant~~ country must justify the choice of survey design and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 2.7.13.2.) of ND and are not routinely vaccinated (e.g. ducks). Surveillance may also target poultry populations at specific risk, for example direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live poultry markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, surveillance of wild birds may be of value in alerting Veterinary Services to the possible exposure of poultry, and particular of free ranging poultry.

**Comment/rationale:** Surveillance of wild birds will help alert Veterinary Authorities to the potential exposure to any poultry, not just free ranging poultry.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as flocks which may be epidemiologically linked to it.

The results of active and passive surveillance are important in providing reliable evidence that no vNDV *infection* is present in a country, *zone* or *compartment*.

## 2. Clinical surveillance

Clinical surveillance aims to detect clinical signs suggestive of ND at the flock level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of vNDV *infection* in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious animals are detected should be considered as infected until evidence to the contrary is produced. Identification of infected flocks is vital to the identification of sources of vNDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in an ~~approved~~ *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

## 3. Virological surveillance

Virological surveillance should be conducted using tests described in the *Terrestrial Manual* to: monitor at risk populations;

- a) confirm suspect clinical cases;
- b) follow up positive serological results in unvaccinated populations or sentinel birds;
- c) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*).

## 4. Serological surveillance

~~Where systematic vaccination is carried out, serological surveillance is of limited value. Serological surveillance cannot be used to discriminate between vNDV and other NDV strains aims at the detection of antibodies against NDV but is not diagnostic of the presence of vNDV. Test procedures and interpretations of results are as described in Chapter x.x.x of the *Terrestrial Manual*. Positive NDV antibody test results can have ~~four~~ five possible causes:~~

**Comment/rationale:** consider deleting the word "systematic" since regardless of whether or not vaccination is 'systematic', it does not change the fact that serological surveillance may be of limited value, particularly if vaccination is widespread.

- a) natural *infection* with NDV;
- b) vaccination against ND (~~whether intentional or not~~);
- ~~c)~~ exposure to vaccine virus;
- ~~ed)~~ maternal antibodies derived from a vaccinated or infected parent flock are usually found in the yolk and can persist in progeny for up to 4 weeks;
- ~~de)~~ non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated flocks must be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative

of ~~active infection~~, virological ~~surveillance methods~~ should be used to confirm the presence of vNDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field ND viruses are available, serological tools should not be used to identify NDV *infection* in vaccinated populations.

#### 5. Use of sentinel poultry

There are various applications of the use of sentinel poultry as a surveillance tool ~~in susceptible populations~~ to detect virus circulation ~~by the presence of clinical disease or seroconversion~~. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel poultry should ~~ideally~~ be immunologically naïve and may be used in vaccinated flocks ~~subject to a risk assessment~~. In case of the use of sentinel poultry, the structure and organisation of the poultry sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel poultry must be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel poultry must be observed regularly for evidence of clinical *disease* and any *disease* incidents investigated by prompt ~~virological~~ laboratory testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel poultry do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel poultry). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population.

Article 3.8.X.4.

### Documentation of ND free status

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article x.x.13.3.

A country declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a surveillance programme in which the ND susceptible poultry population undergoes regular surveillance planned and implemented according to the general conditions and methods described in these guidelines.

~~A country, *zone* or *compartment* may be considered free from ND when it has been shown that vNDV infection has not been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix x.x.x. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.~~

~~If infection has occurred in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix x.x.x. has been carried out during that three-month period.~~

#### 1. Countries declaring freedom from ND for the country, *zone* or *compartment*

In addition to the general conditions described in the *Terrestrial Code*, a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective surveillance programme. The surveillance programme should be planned and implemented according to general conditions and methods described in this Appendix to demonstrate absence of vNDV *infection* in poultry during the preceding 12 months.

~~This requires the support of an *approved laboratory* capable of identification of vNDV infection through virus detection and antibody tests described in the *Terrestrial Manual*.~~

## 2. Additional requirements for countries, zones or compartments that practice vaccination

~~Vaccination against ND may be used for risk management (to reduce the risk of introduction and subsequent transmission) or as part a component of a *disease prevention and control* programme. The level of flock immunity required to prevent transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. The vaccine used must also comply with the provisions stipulated for ND vaccines in of the *Terrestrial Manual*.~~

In ~~all~~ vaccinated populations there is a need to perform surveillance (Article x.x.x.x.) to ensure the absence of vNDV circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The surveillance must be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*. Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 3.8.X.5.

## **Countries, zones or compartments regaining freedom from ND following an outbreak**

~~In addition to the general conditions described in Chapter 2.7.13., a A country regaining country, *zone* or *compartment* freedom from vNDV infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel poultry may facilitate the interpretation of surveillance results.~~

A country declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of ~~an active~~ a surveillance programme in which the ND susceptible poultry population undergoes regular ~~clinical examination and active surveillance~~ planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should give at least the same confidence that can be achieved by testing a ~~randomized representative sample of the populations at risk.~~